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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,937	05/30/2001	Bin Wu	PP-01623.002	8716

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Chiron Corporation
Intellectual Property
P. O. Box 8097
Emeryville, CA 94662-8097

EXAMINER
LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
1636	8

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/870,937	Applicant(s) WU ET AL.	
	Examiner David Lambertson	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 20-26, drawn to an isolated KIAA0175 inhibitor (antisense) and therapeutic compositions thereof, classified in class 536, subclass 24.5.

II. Claims 1, 20, 21 and 26, drawn to an isolated KIAA0175 inhibitor (ribozyme) and therapeutic compositions thereof, classified in class , subclass .

III. Claims 1, 20, 21 and 26, drawn to an isolated KIAA0175 inhibitor (antibody or antibody fragment) and therapeutic compositions thereof, classified in class , subclass .

IV. Claims 1, 20, 21 and 26, drawn to an isolated KIAA0175 inhibitor (protein or polypeptide) and therapeutic compositions thereof, classified in class , subclass .

V. Claims 1, 20, 21 and 26, drawn to an isolated KIAA0175 inhibitor (small molecule) and therapeutic compositions thereof, classified in class , subclass .

VI. Claims 6, 7 and 19, drawn to a method for decreasing the expression of KIAA0175, classified in class 536, subclass 24.5.

VII. Claims 8 and 9, drawn to a method for decreasing the expression of p21, classified in class 536, subclass 24.5.

VIII. Claims 10 and 11, drawn to a method for decreasing the expression of p53, classified in class 536, subclass 24.5.

IX. Claims 12-15, drawn to a method for increasing the chemosensitivity or radiosensitivity of a cell, classified in class 514, subclass 44.

X. Claims 16 and 17, drawn to a method for reducing the side effects of cancer therapy, classified in class 514, subclass 44.

XI. Claim 18, drawn to a method for treating neoplastic disease, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions Groups I-V are all unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. An antisense molecule (Group I), a ribozyme (Group II), an antibody or antibody fragment (Group III), a protein or polypeptide (Group IV) and a small molecule (Group V) all have different structures and functions. Thus, a search of one group would not be co-extensive with a search of the other group, hence said search would be burdensome.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences listed in claims 5 and 25 are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a

single application. Under this policy, a single independent and distinct nucleotide sequence will be examined in a single application.

Claims 5 and 25 specifically claim antisense SEQ ID NOS 1, 3 and 5, which are targeted to and modulate the expression of KIAA0175. Although the antisense sequences for each group claimed each target and modulates the expression of the same respective gene, the instant antisense sequences are considered to be unrelated since each antisense sequence claimed is structurally and functionally independent and distinct for the following reasons: each antisense sequence has a unique nucleotide sequence and each antisense sequence targets a different and specific region of KIAA0175. Furthermore, a search of more than one (1) of the antisense sequences claimed in 5 and 25 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense sequences. In view of the foregoing, one (1) antisense sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicant is required to elect one (1) corresponding antisense sequence when electing a group as set forth above.

Inventions Groups I-V and Groups VI-XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process. For example, the antisense molecule can be used as a diagnostic

probe for KIAA0175 mRNA in a Northern blot. Therefore a search of one would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Group VI and Group VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. A method for decreasing KIAA0175 expression (Group II) is unrelated to a method for decreasing the expression of p21 (Group III) because in each case, the expression of a different gene is being decreased, thus each method is directed to a different outcome. Therefore, a search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Groups VI and VII and Group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. A method for decreasing KIAA0175 expression (Group VI) and a method for decreasing p21 expression (Group VII) are unrelated to a method for decreasing the expression of p53 (Group VIII) because in each case, the expression of a different gene is being decreased, thus each method is directed to different outcomes. Therefore, a search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Groups VI, VII and VIII and Group IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. A method for decreasing KIAA0175 expression (Group VI), a method for decreasing p21 expression (Group VII) and a method for decreasing the expression of p53 (Group VIII) are unrelated to a method for increasing the chemosensitivity of cells (Group IX) because the methods encompass different, unrelated steps and are directed to different outcomes. Therefore, a search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Groups VI, VII and VIII and Group X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. A method for decreasing KIAA0175 expression (Group VI), a method for decreasing p21 expression (Group VII) and a method for decreasing the expression of p53 (Group VIII) are unrelated to a method for reducing the side effects of cancer therapy (Group X) because the methods encompass different, unrelated steps and are directed to different outcomes. Therefore, a search of one group would not be co-extensive with a search of the other hence said search would be burdensome.

Inventions Groups VI, VII and VIII and Group XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. A method for decreasing

KIAA0175 expression (Group VI), a method for decreasing p21 expression (Group VII) and a method for decreasing the expression of p53 (Group VIII) are unrelated to a method for treating neoplastic disease (Group XI) because the methods encompass different, unrelated steps and are directed to different outcomes. Therefore, a search of one group would not be co-extensive with the search of the other hence said search would be burdensome.

Inventions Group IX and Group X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. A method for increasing the chemosensitivity of cells (Group IX) is unrelated to a method for reducing the side effects of cancer therapy (Group X) because the methods encompass different, unrelated steps and are directed to a different outcome. Therefore, a search of one group would not be co-extensive with the search of the other hence said search would be burdensome.

Inventions Group IX and X and Group XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. A method for increasing the chemosensitivity of cells (Group IX) and a method for reducing the side effects of cancer therapy (Group X) are unrelated to a method for treating neoplastic disease (Group XI) because the methods encompass different, unrelated steps and are directed to different outcomes. Therefore,

a search of one group would not be co-extensive with the search of the other hence said search would be burdensome.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, and so on, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
July 31, 2002

DAVID GUZO
PRIMARY EXAMINER